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Greenfield et al.

[11] **3,980,436**

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[54] **ANALYTIC TEST DEVICE**

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[52] **U.S. Cl.** ..... **23/253 R;** 23/253 TP; 23/259; 128/2 F

[51] **Int. Cl.²** **G01N 31/22;** G01N 1/10; A61B 1/10

[58] **Field of Search** ..... 23/259, 253 TP, 253 R, 23/292; 128/2 F, 295; 73/421 R

[56] **References Cited**

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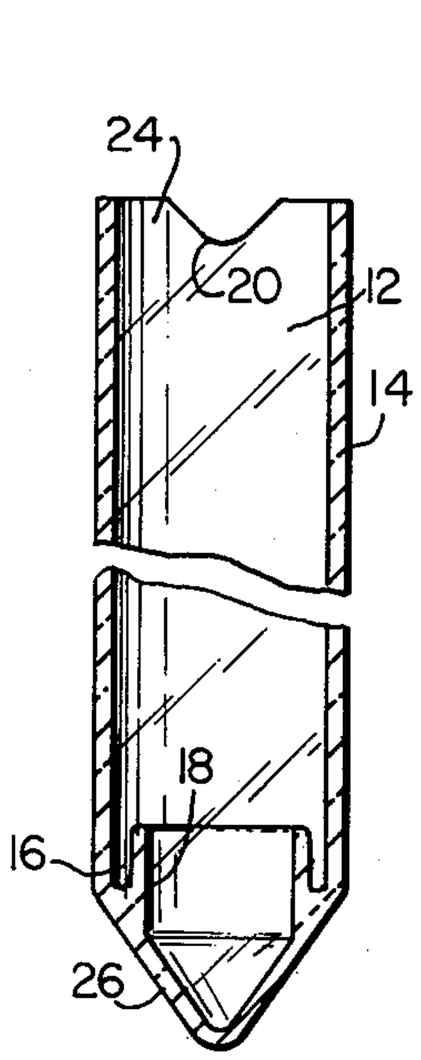
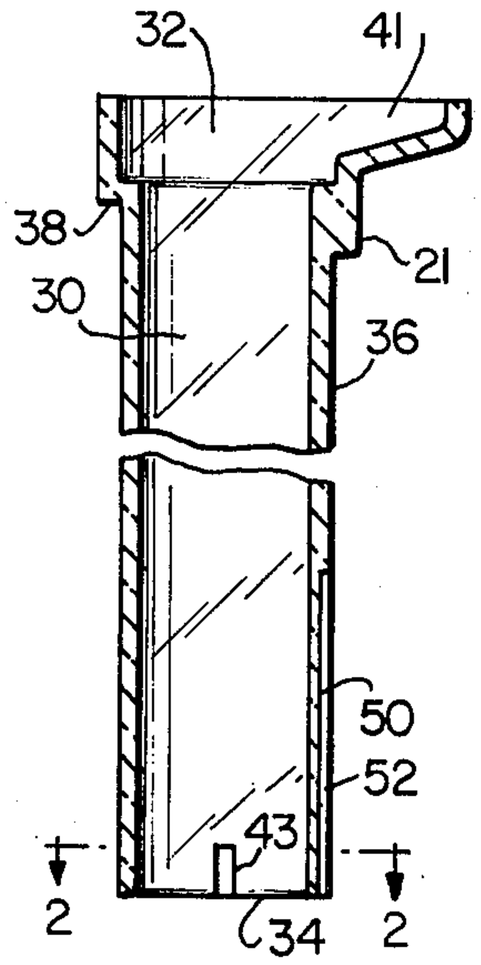
[57] **ABSTRACT**

An analytic test device of a one time use type formed by concentrically disposed tube and sleeve members. A test reagent is present in the annular region between tube and sleeve. A liquid sample placed inside the tube is unable to enter the reagent containing annular region until relative movement between tube and sleeve opens a passage for sample flow into the annular region and contact with the test reagent.

The test device is particularly adapted to testing urine samples.

6 Claims, 6 Drawing Figures





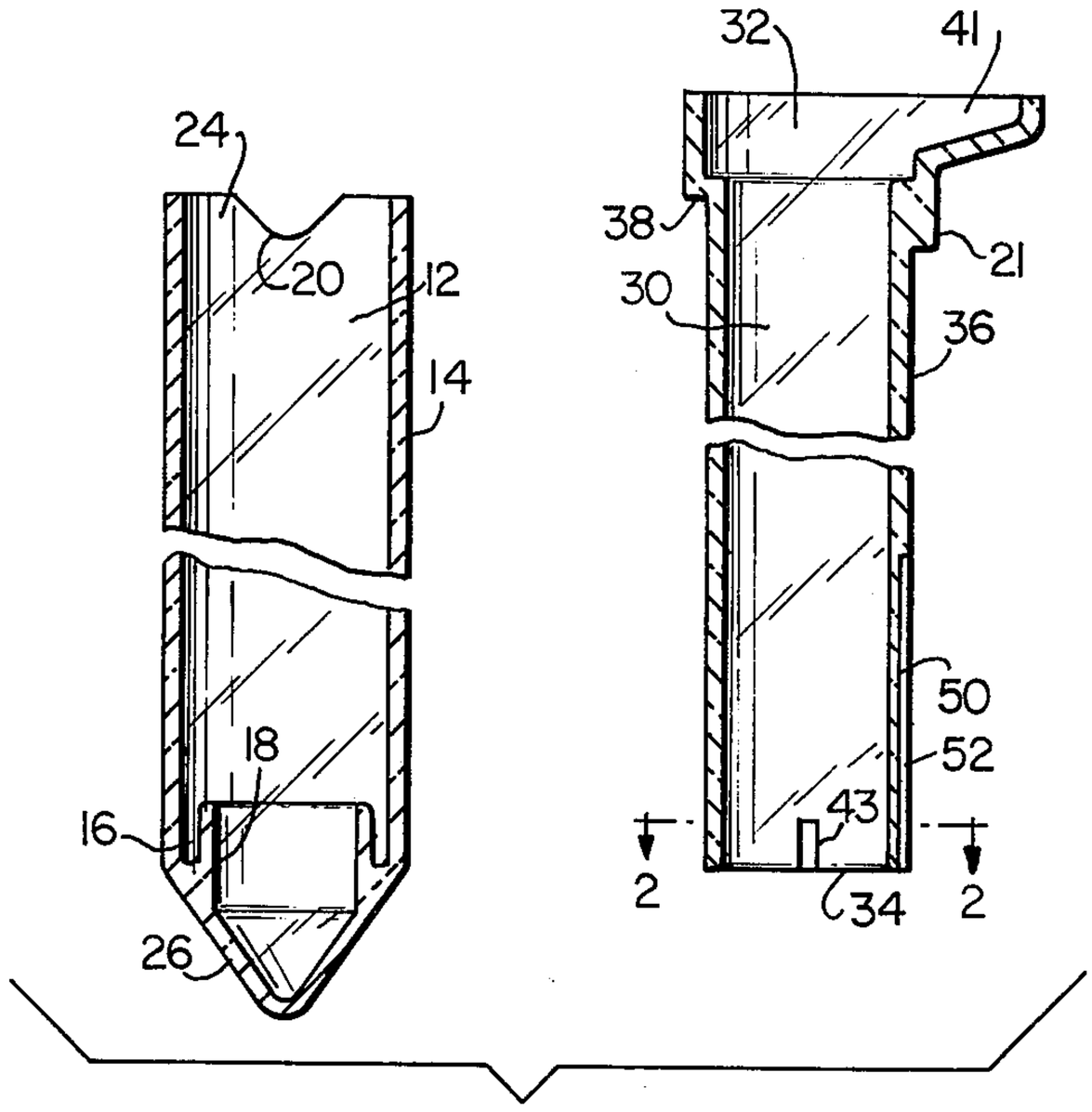


FIG. 1

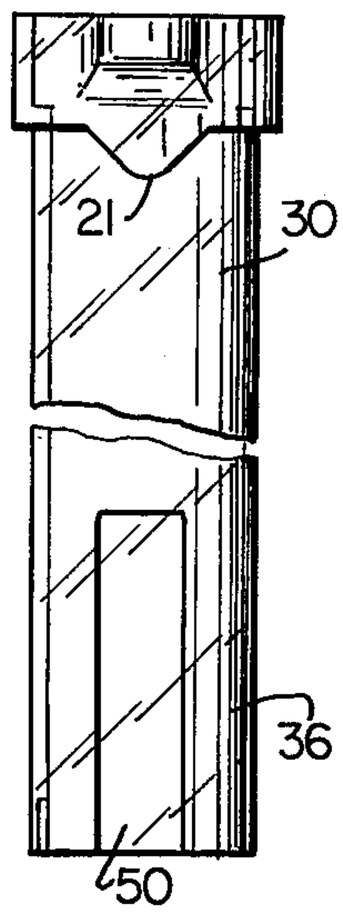


FIG. 3

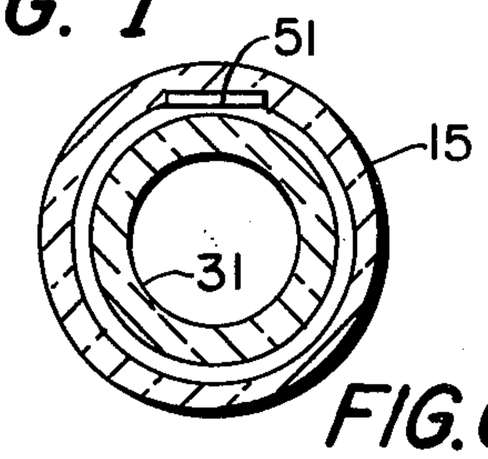


FIG. 6

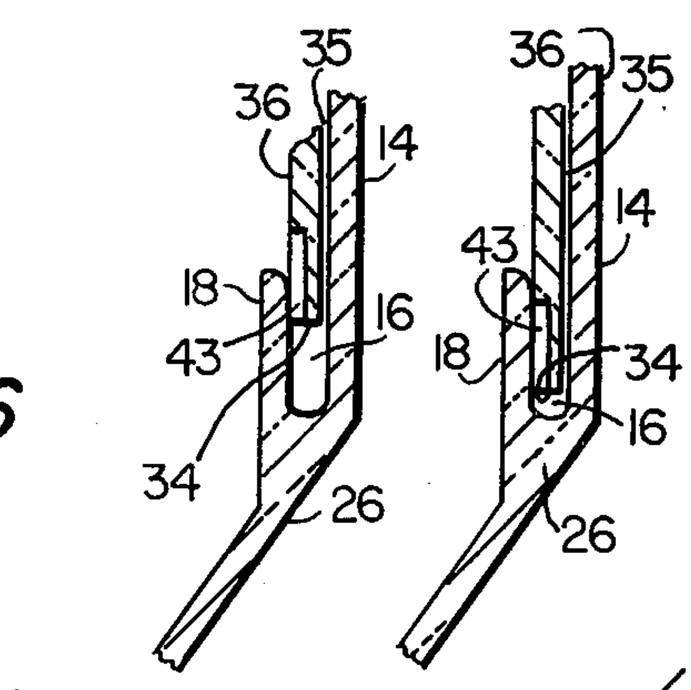


FIG. 4

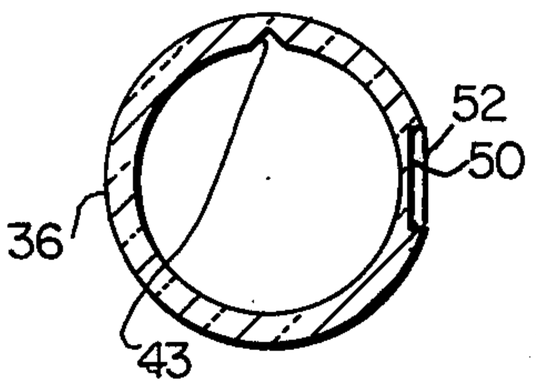


FIG. 2

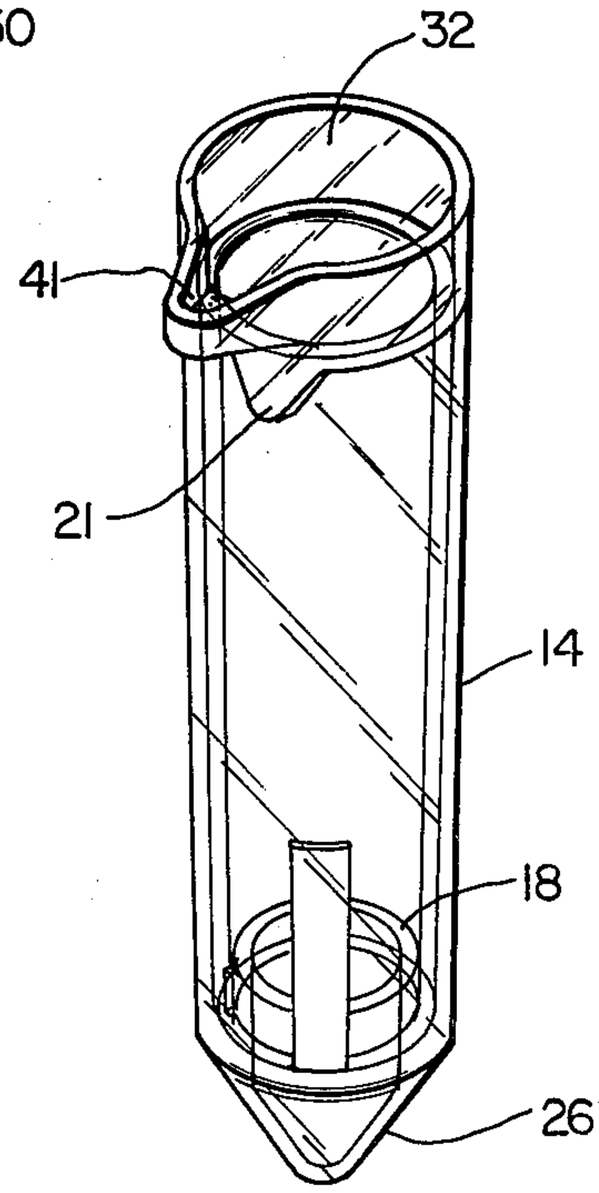


FIG. 5

ANALYTIC TEST DEVICE

BACKGROUND OF THE INVENTION

In a common laboratory testing system for medical purposes, the laboratory technician dips chemically impregnated paper strips into the sample or specimen (e.g. of urine) and observes a color change in the strip, the change depending on the composition of the strip impregnant and the biochemical reactions involved. Laboratory analyses are very quickly and easily conducted with the strips.

Notwithstanding simplicity (at least insofar as the technician is concerned), closer control of the test is desirable, including, for example, a limit on the quantity of urine in contact with the strip. It has now been found possible to construct a collecting and testing unit that greatly facilitates conduct of the analytical test and reduces chances for contamination and mistakes.

SUMMARY OF THE INVENTION

Briefly stated, the present invention involves an integrated sample collection and testing unit formed from two concentric tubular components. One component constitutes a sample chamber hereinafter called the tube, and the other component is a sleeve member open top and bottom and sized to concentrically interfit internally or externally with the first component, i.e. the tube. The tube-sleeve structure provides an annular region between adjacent tube and sleeve side walls. This annular region can be sealed off from the sample or opened to the sample as desired without leaking sample from the assembled testing unit.

The tube or sleeve wall surface facing the annular region is provided with one or more recesses, in which can be placed analytical test reagents. Paper strips impregnated with the analytic test reagents are a convenient and preferred reagent insert.

Means are provided to seal the annular region against sample flow thereinto, such means normally being a fluid tight sealing structure. However, the sealing means may constitute an interfit between tube and sleeve tight enough to avoid leakage. However, an important aspect of this invention is that tube and sleeve are relatively movable, so that the tube and sleeve interfit may be shifted as desired from a fluid tight sealed position to an open position wherein sample flows into the annular region. In the open position a controlled amount of sample flows into the annular region, wets the test reagent to cause the test reaction. Forming the outer component from a transparent material allows the test results to be seen by the technician, or be measured by an optical instrument.

DETAILED DESCRIPTION OF THE INVENTION

For further understanding of the present invention, reference is now made to the attached drawings, wherein a preferred embodiment of test unit is illustrated. In the drawing:

FIG. **1** is a cross-section through the tube and sleeve components in an unassembled state;

FIG. **2** is a section taken along line **2—2** of FIG. **1;**

FIG. **3** is a side view of the sleeve;

FIG. **4** is a partial cross-section illustrating the sealing fit of the test unit; and

FIG. **5** is a pictorial view of the test unit;

FIG. **6** is a cross-section of a different mode of tube and sleeve.

As may be seen in FIG. **1,** the tube or sample container **12** is the outer component and is formed with an imperforate side wall **14,** open top rim **24** and a sealed bottom well **26,** all of which makes tube **12** suitable for liquid sample retaining purposes. Just above bottom well **26** is a U-shaped channel **16** sized and shaped for close interfit of a cylindrical sleeve against the inner channel wall **18.** At the top **24,** the side wall **14** contains a gently curved slot **20.** It may be noted that tube **12** has a structure capable of being formed by plastic molding techniques in large numbers relatively inexpensively.

Also shown in FIG. **1** is a sleeve **30,** adapted to interfit with container tube **12** to form a complete sample collecting vessel and test device. To this effect, sleeve **30** is formed with open top **32** and open bottom **34** and with an imperforate side wall **36** sized for a concentric relationship with the inside surface of side wall **14** on container tube **12.** Sleeve **30** is formed with an annular shoulder **38** thereon which seats on the top rim **24** of container tube **12.** The sleeve **30** is supported by rim **24.**

The side wall of sleeve **30** near the bottom **34** thereof may be tapered and bevelled to ensure entry into channel **16** and to bear against channel wall **18.** Normally sleeve bottom **34** is clear of the bottom of channel **16.** Consequently, the assembled tube **12** and sleeve **30** interfit to form the test device **10** shown in FIG. **5** with container tube **12** and sleeve **30** having a watertight but relatively rotatable relationship.

For user convenience the top of sleeve **30** is formed with a pouring lip **41.**

In the preferred embodiment illustrated in the drawing, cooperating means are provided to facilitate assembling the test device **10** locked into the sealed position. Allusion has already been made to the slot **20.** A cam **21** (which conveniently may be formed under pouring lip **41**) extends down as an extension of shoulder **38,** with cam **21** being in slot **20** in the sealed position.

The side wall **36** of sleeve **30** has a V-shaped notch **43** formed on the inside surface at the bottom of the sleeve. The notch **43,** which may be rather short (e.g. 0.250 inch) is related to the depth of slot **20.** When cam **21** is in slot **20,** and sleeve **30** seats on the rim of tube **12,** notch **43** is completely recessed inside channel **16** with an un-notched portion of the inside wall surface of side wall (above notch **43**) bearing against channel wall **18** sealing the annular region **35** against sample leakage, as is shown in FIG. **4.**

However, when tube **12** and sleeve **30** are rotated relative to each other, e.g. 90°, cam **21** rides up out of slot **20** onto the rim **24** forcing a longitudinal displacement of tube and sleeve which lifts the bottom **34** of sleeve **30** up inside channel **16.** The V-notch **43** is no longer concealed behind channel wall **18,** as is illustrated in FIG. **4.** The longitudinal displacement has shifted test device **10** to an open position. Sample liquid flows down through notch **43** into the bottom of channel **16** then up into annular region **35,** wetting a test reagent **52** disposed in a recess **50,** which recess is conveniently formed in the outside surface of sleeve wall **36.**

Since the interfit of tube **12** and sleeve **30** provides relatively little volume for any liquid in annular region **35,** capillary action helps to create liquid sample migration into region **35,** but only a limited volume of liquid can transport to react with test reagent **52.** If strict

volume control is desired and back diffusion of reactants prevented, test device **10** can be shifted back to the closed position by relative rotation back to the closed position after the test reagent **52** is adequately wetted.

It may be noted that sleeve **30** has a structure capable of being formed by plastic molding techniques in large numbers and relatively inexpensively. Recess **50** and notch **43** extend to the bottom **34** of the sleeve, which facilitates fabrication, and for that matter insertion of a reagent containing test strip **52** into recess **50.**

In any event the test reagent **52** (desirably in strip form) is placed into recess **50,** then the reagent containing sleeve **30** is inserted into tube **12** with tube and sleeve disposed in the closed or sealed position. The sealed position is normally employed for packaging of test unit **10** and shipping. Test reagent **52** is protected by the sealed character of the sealed position. If desired, a stopper (not shown) may be included in the package so that the open mouth **32** of test unit **10** can be closed (after sample has been placed inside) to prevent odor or spillage.

To analyze the sample placed inside test unit **10,** the user rotates the container **12** and sleeve **30** relative to one another, e.g. 90° to the open position. The (urine) sample flows through notch **43** to the recess **50** and there contacts the reagent strip **52.** Thereafter the user rotates or back rotates container **12** until the closed position is reached. To the extent that the opened position illustrated in FIG. **4** can be considered the active position, a subsequent closed relationship as also is shown in FIG. **4** constitutes a deactivated position which prevents the sample urine from further contact with the test reagents (if further contact is not desired).

Analytic tests of the nature contemplated for use with the test device of the present invention usually involve color change; the nature of the color change constitutes the test result. Accordingly, once sleeve and tube have been rotated to the deactivated or closed position, the technician is free to observe the color change of the reagents through the transparent side wall **14** of tube **12.** After the user has interpreted, recorded, etc. the test results, the test device **10** with sample therein is still available for further use, e.g. as a centrifuge tube for measuring sediment, etc.

Once used, the test device **10** may be discarded. The one time use concepts embodied in the illustrated test device of the present invention are advantageous. Spillage, odor, and the unpleasant handling characteristics of prior art test systems can be avoided by one time use of this test device.

The materials involved in the test device of the present invention form no part of the invention and the actual analytic tests are known to the prior art. Tube **12** and sleeve **30** should be transparent components and for example, may be plastic materials such as polyethylene, polycarbonates, and the like, injection molded into the desired shape. The reagent can of course be inserted as part of the assembly of sleeve **30** and tube **12.** Test reagents impregnated on paper or paper like materials supports can be obtained commercially. Such pre-prepared strips may be cut to size and placed into the recess or recesses **50** of sleeve **30.**

It should be appreciated that the structure illustrated by the drawing represents but a single, although preferred, embodiment of this invention. The recess **50** may of course be placed in the tube wall rather than in the sleeve wall, as is illustrated in FIG. **6** wherein recess **51** is present in the wall of tube **15** rather than in sleeve **31.** Also, the tube and sleeve concept may be embodied by an external sleeve and internal tube. Still other modes are contemplated. Thus, a liquid-tight fit between tube and sleeve can be employed with window apertures in the inside component wall alignable through rotation and/or longitudinal displacement into reagent containing recesses in the outside component wall. In short, considerable structural variations are contemplated as being encompassed within the scope of this invention and of the hereto appended claims.

What is claimed:

1. An analytic test device and receptacle for a liquid test sample which comprises:

a closely adjacent concentric tube and sleeve relatively movable one to the other, the concentric fit of tube and sleeve providing an annular region therebetween, the sleeve constituting the inner member and being adapted to contain a liquid sample therein;

a recess-in the tube or sleeve wall surface bounding said annular region, said recess containing a test reagent therein;

sealing means provided on the tube for retaining the bottom rim of said sleeve in a fluid-tight seal against sample liquid migration under said rim into said annular region, the seal of said sealing means being opened by relative movement of tube and sleeve whereby sample liquid helped by capillary action migrates into said annular region and into contact with test reagent.

2. The analytic test device of claim **1** wherein the tube and sleeve are transparent whereby color change in the test reagent is visible.

3. An analytic test device and receptacle for a liquid test sample which comprises:

a closely adjacent concentric tube and sleeve relatively movable one to the other, the concentric fit of tube and sleeve providing an annular region therebetween and said sleeve being an internal member adapted to contain a liquid sample therein;

a recess in the sleeve wall surface facing said annular region, said recess containing a test reagent therein;

sealing means at the juncture of the sleeve bottom and said tube for preventing liquid sample from migrating past the sleeve bottom into said annular region; and

a liquid passage means at the sleeve bottom, opened by relative movement of tube and sleeve whereby sample liquid helped by capillary action migrates through said liquid passage means into said annular region and into contact with the test reagent.

4. The analytic test device of claim **3** wherein a U-shaped channel in said tube adjacent the bottom thereof receives the sleeve bottom and acts as the sealing means.

5. The analytic test device of claim **4** wherein said sleeve extends longitudinally beyond said tube and seats upon an open rim top surface of said tube and wherein the sleeve bottom seals against the channel wall.

6. The analytic test device of claim **4** wherein a notch at the sleeve bottom constitutes the liquid passage means, said notch being sealed off in the U-shaped channel until longitudinal relative movement of sleeve and tube raises said notch out of the U-shaped channel.

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